Alleged subsidization of physicians by inflated AWPs

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS
	Judge Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	

MERITS REPORT OF LINDA A. HAEGELE, M.D.

MARCH 20, 2006

HIGHLY CONFIDENTIAL

symptoms, counsel the patient about side effects and nutrition, and conduct a physical examination. Before chemotherapy is administered, the clinical assistant performs the blood count tests to ascertain whether the patient's complete blood count is adequate to proceed with treatment that day.

If the patient cannot be given chemotherapy that day, my receptionist schedules an appointment for another day. If the patient cannot tolerate the side effects of a particular drug regimen or if studies indicate disease progression, modifications are made in the particular drug regimen or an alternative drug regimen is prescribed and administered after extensive discussion with the patient and caregivers.

On occasion, new clinical data influences the patient's course of treatment. For example, Herceptin is a monoclonal antibody that is FDA-approved for treatment of metastatic breast cancer to block the HER2 protein in cancer cells and stop the growth of HER2-positive cancer cells. About one out of every four breast cancers is HER2-positive and this probably represents a more aggressive tumor than HER2-negative breast cancers. Since remarkable clinical data discussed in a 2005 ASCO meeting demonstrated Herceptin's efficacy in the adjuvant setting, I am currently utilizing Herceptin as adjuvant chemotherapy for HER2/Nu+ breast cancer patients.

41. *Patient Advocacy:* Frequently, it is necessary to obtain approval or pre-certification from the patient's insurance before proceeding to administer specific therapy. This process often entails prolonged telephone contact with the carrier, before therapy care be initiated. For example, before I prescribe Herceptin to a patient, I ascertain that the health plan will reimburse me since Herceptin is a patented single-source drug which is very expensive. Fortunately, the health plans are reimbursing Herceptin for off-label use because the patient advocacy groups have publicized Herceptin's effectiveness as adjuvant chemotherapy and the scientific/clinical data is now established. The time spent by me and my staff obtaining such insurance approval is never reimbursed.

VI. BILLING AND REIMBURSEMENT FOR OFFICE-BASED ONCOLOGY

42. In the previous section, I have outlined some, but not all, of the time, expertise and expense it takes to run my medical oncology practice – with special emphasis on that which is not compensated by payors. In this section, I discuss the goods and services that are compensated by the public and private payors with whom I work.

43. At the outset, I must state that billing and reimbursement for medical oncology is very bureaucratic, arcane and complex in both the public and private sphere. Very generally, I am reimbursed for (1) office visits; (2) blood tests; (3) the service of administering drugs and (4) the drugs themselves. As I will show, the reimbursement amounts for the first three have historically been so low that, had I not derived significant revenue from the drugs themselves, it would not have been economically feasible for me to provide office-based chemotherapy.

44. My office accepts reimbursement from Medicare and from various private payors. Twenty percent of my patients have coverage through Medicare Part B or Part C (the Medicare Advantage HMOs known as Health Partners Senior Partners and Elder Health). Most of my Medicare Part B patients have Medigap coverage through United Healthcare or Blue Cross/Blue Shield. Another 10% of my patients have a Medicaid HMO plan through Keystone Mercy Health Plan (operated by Independent Blue Cross) or AmeriChoice.[3] The remainder of my patients have private health insurance: 30% have coverage through Preferred Provider Organization ("PPO") plans including Personal Choice from Independence Blue Cross, Aetna US Health Care and Pennsylvania Blue Shield; another 30% have coverage through Health Management Organization ("HMO") plans including Aetna US Health Care, Keystone Health Plan East (operated by Independent Blue Cross), Amerihealth and Cigna; and another 10% have a commercial insurance plan through, among others, United Health Care and UFCW Local 56 Fund.

Being a sole practitioner in a metropolitan area, I have little ability to negotiate with the commercial payors. They dictate the terms of the contract and I can agree to their terms or not participate in their networks. Finally, especially with commercial insurance, my patients have some obligation to pay either a fixed or percentage co-payment. At the end of this section, I relate my experience in trying to collect these co-payments.

45. My office bills Medicare using the HCFA Common Procedure Coding System (HCPCS). The HCPCS codes have been adopted by the private payors so we bill the health plans using the same coding system as Medicare.

46. HCPCS comprises three types of codes, only two of which are relevant to my office. HCPCS Level I codes are Current Procedural Terminology (CPT) codes, developed and updated annually by the American Medical Association. These CPT Codes generally correspond to medical procedures and are broken down by categories based on medical specialties.[4] HCPCS Level II codes begin with a single letter (A-V) followed by four numeric digits and are used to identify products, supplies, and services not included in the CPT codes. For medical oncology, the relevant HCPCS Level II Code is the "J-Code," which is for the drugs that are administered to the patients.

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[3] I believe that I am the only office-based oncologist in the Northeast Philadelphia area that will accept these Medicaid HMO patients because the reimbursement allowances for them are so poor compared to those by Medicare and other commercial payors. Other than the two Medicaid HMO plans described above, even I do not accept Medicaid patients because I would lose money if I treated them. If the patient has a Pennsylvania Medicaid Access card, I send that patient to Temple Hospital, a state-related institution, because I cannot afford to provide care for that patient.

[4] The CPT codes are divided into six sections: Evaluation and Management (E/M) (CPT Codes 99201-99499); Anesthesia (CPT Codes 00100-01999); Surgery (CPT Codes 10040-69999); Radiology (CPT Codes 70010-79999); Pathology and Laboratory (CPT Codes 80002-89399) and Medicine (CPT Codes 90700-99199). The Level III HCPCS codes, not used by my office, are local codes assigned and maintained by the individual state Medicare carriers to describe new procedures and services not listed under Level I and II codes. These codes begin with a single letter (W-X) followed by four numeric digits.

47. *CPT Codes- Office Visit and Consultations*: For medical oncology, the office visits are billed using the Evaluation and Management or "E/M" CPT Codes. The E/M CPT codes describe the office visits and consultations, which must be face-to-face; I cannot bill for the hours I spend with patients over the telephone or on my own with their insurers or other family members.

There are five CPT codes for an initial office consultation (CPT Codes 99241 to 99245, often referred to as Level I-V). I bill my E/M services as an initial consultation (CPT Codes 99241 to 99245) if the patient is referred to me by another physician who requests my advice or opinion about the diagnostic and/or treatment options. In my practice, the Code for an initial visit is usually 99245 or Level V, because it requires comprehensive documentation of the patient's history, a multi-system physical examination, a complex diagnosis and evaluation of various treatment and pain management options and/or referrals to other specialists. I usually spend at least an hour with the patient. Afterward, I create a written report of my findings and recommendations. The written report must be sent to the referring physician.

Medicare and the private payors below have reimbursed my practice the following amounts for a Level V initial office visit (CPT Code 99245) from 2002-2005:

	Reimbursement Amount for Level V Initial Office Visit			
Provider	**2002**	**2003**	**2004**	**2005**
Medicare	$193.26	$193.26	$222.23	$225.81
Aetna	$ 100.00	$100.00	$194.00	$194.00
Health Partners of Philadelphia	$53.41	$53.41	$59.82	N/A
Independence Blue Cross	$120.00	$120.00	$160.00	$160.00

In 2004 and 2005, Medicare, Aetna, Independence Blue Cross, and Health Partners of Philadelphia increased their reimbursement for the Level V initial office visits.

Subsequent office visits are billed under Codes 99211-99215, which again reflect the differing levels of E/M services provided and which for billing purposes must be fully documented in the patient's records. I generally bill these subsequent visits as a Level III (CPT code 99213), Level IV (CPT Code 99214) or Level V (CPT Code 99215) E/M services. The most frequent Code billed is a Level V established patient visit (CPT Code 99215).

Medicare and some of the private payors have reimbursed my practice the following amounts for a Level V established patient visit (CPT Code 99215):

	Reimbursement Amount for Level V Established Patient Visit			
Provider	**2002**	**2003**	**2004**	**2005**
Medicare	$102.87	$102.87	$120.10	$121.17
Aetna	$ 50.00	$50.00	$105.00	$105.00
Health Partners of Philadelphia	$97.27	$112.27	$62.57	$62.57
Independence Blue Cross	$74.00	$74.00	$86.00	$86.00

Medicare, Aetna and Independence Blue Cross increased their payment for the Level V established patient visits in 2004 and 2005. Health Partners of Philadelphia decreased its reimbursement in 2004 and 2005.

I view the 2002-2003 reimbursement amounts for initial and subsequent office visits as highly inadequate if divorced from money I also received from buying and billing for the drugs provided to my patients. I often spend more than an hour with the patient on the initial visit. While there is, theoretically, a CPT Code for an "extended" visit, both Medicare and the private payors make the required forms for qualification so onerous and difficult to satisfy that, as a practical matter, I am better off writing off my time rather than trying to qualify. It is my understanding from discussions with other medical oncologists that they also do not bill using the extended CPT code because of the burdensome documentation requirements. Further, as noted above, I am not compensated at all for the time I spend on the phone counseling my patients and their families or coordinating care with other physicians. Finally, the low reimbursements for office visits do not adequately compensate my office for my staff's time arranging the visits, assisting the patients during the visits and the paperwork of processing my reports and bills.

In 2004 and 2005, Medicare and most private payors increased their reimbursement for office visits. Medicare raised its reimbursement rate for office visits at the same time it lowered reimbursement for drugs in 2004.

48. *CPT Codes-Laboratory*: My office used CPT Codes 85023[5] and 85025 to bill Medicare and private payors for performing the complete blood count lab work. My office has an on-site lab because I need to determine the patient's white blood, hemoglobin and platelets counts before my nurses can administer chemotherapy. Medicare and the private payors pay me very little for the lab work.

[5] CPT Code 85023 was deleted effective January 1, 2003 and replaced with CPT Code 85025 to describe the complete blood count test. At that time, some private payors allowed my office some leeway. They reimbursed under CPT Code 85023 up to six months after its deletion. Beginning in January 2006, the private payors no longer provide this leeway; a failure to bill under the proper code will lead to a denial of the claim.

For the complete blood count lab work (CPT Codes 85023 and 85025), my office was paid the following fees from 2002-2005:

	Reimbursement Amount for Blood Count Lab Work			
Provider	2002	2003	2004	2005
Medicare	$11.71	$10.74	$10.86	$10.86
Aetna	$13.00	$9.00	$7.00	$7.00
Health Partners of Philadelphia	N/A	$10.74	$6.54	$6.54
Independence Blue Cross	$9.00	$9.00	$9.30	$9.30

In addition, for the blood draw to do the blood count, Medicare paid $3 under CPT Code 36415 (collection of venous blood by venipuncture). The health plans also reimbursed my office $3 for the blood draw.

Given the low reimbursements, I lose money operating the lab. The lab reimbursement does not adequately reimburse me for the lab assistant's time drawing the blood, running the tests and analyzing the results, my supervision time, the cost of renting the Beckman-Coulter blood analyzer ($877 per month), maintaining the state license (about $300 per year) and the necessary supplies such as bandages, swabs, gloves, gowns, tubing and test tubes.

49. *CPT Codes- Administration of Drugs*: My office bills Medicare and private payors using several drug administration codes. Prior to January 1, 2005, administration of drugs was billed using CPT codes.[6] The *infusion* of saline (for hydration), antiemetics (to reduce nausea), diuretics (to reduce bloating), or any other nonchemotherapy drug was billed using CPT Codes 90780 to 90781 (therapeutic or diagnostic infusions). Billing for *injection* of nonchemotherapy drugs is based upon whether the agent is a subcutaneous or intramuscular injection (CPT Code 90782), an intra-arterial injection (CPT Code 97083) or an intravenous injection (CPT Code 90784). Administration of the chemotherapy agents themselves was billed using CPT Codes 96400 to 965425. These various CPT codes for chemotherapy administration again correspond with the method used to administer or deliver the drug to the patient, i.e. whether it was administered by *injection*, *infusion* or *IV push* and whether it is was administered in the first hour of a patient treatment session or in a later hour.[7]

[6] In 2005, the Centers for Medicare & Medicaid Services (CMS) replaced the drug administration CPT codes with G codes. CMS added several new G codes that described the administration of additional sequential drugs. These new codes acknowledge the additional work and practice expense associated with the provision of multiple drugs.

[7] There are three methods to administer the drugs: injection, IV push and infusion. An injection is a dose of drug injected into the body with a syringe by a nurse or physician. If the injection is administered through the skin (subcutaneous injection), the drug is sequestered in a localized area, being forced into the interstitial fluid that surrounds the local cells and capillaries. The drug will enter the bloodstream via these local capillaries. Because of the limited physical dispersion of the drug dosage, the absorption of drugs administered subcutaneously tends to be slow and uniform. Some drugs have irritant or caustic effects

In 2002 and 2003, the amounts allowed by Medicare and the private payors for the drug administration codes my office most heavily utilized were as follows:

Code	Description	Year	Medicare	Aetna	Health Partners of Philadelphia	Independence Blue Cross
90780	IV infusion for therapy/ diagnosis; up to one hour	2002	$42.72	$45.00	$41.11	$38.00
		2003	$42.72	$43.00	$41.11	$38.00
90781	IV infusion therapy/ diagnosis; add'l hour	2002	$21.37	$46.00	$21.09	$19.00
		2003	$21.37	$22.00	$21.09	$19.00
90782	Therapeutic/diagnostic injection; subcutaneous or intramuscular	2002	$4.07	$4.83	$4.18	$2.30
		2003	$4.07	$4.29	$4.28	$2.30
96408	Chemotherapy admin., push technique	2002	$36.97	N/A	$35.86	$30.00
		2003	N/A	$19.00	N/A	$30.00
96410	Chemotherapy admin., infusion; first hour	2002	$58.61	$62.00	$48.00	$52.00
		2003	$58.61	$48.42	$48.00	$52.00
96412	Chemotherapy admin., infusion; add'l hour	2002	$43.85	$69.83	$48.00	$47.00
		2003	$43.85	$44.00	$48.00	$47.00

Not only were these amounts insufficient to cover my expenses in connection with performing the administration services; oftentimes I received no compensation for certain services. For example, prior to 2005, the Medicare rules for drug administration did not take into consideration the extra expenses associated with the provision of drug regimens composed of multiple chemotherapy agents in one session. Under CPT Code 96408, my office was paid for only one push administration per day for a patient regardless of the number of chemotherapy drugs actually administered to the patient by push that day. Similarly, if the infusion of saline, an antiemetic, or any other nonchemotherapy drug (normally reimbursed under CPT Codes 90780 and 90781) was administered concurrently with the chemotherapy infusion (CPT Codes 96410, 96412, or 96414), the infusion under CPT Codes 90780 or 90781 was disallowed.

upon local tissues that will cause the skin to slough off if administered subcutaneously. These problems can be minimized by administering the drugs deeply into the muscle mass (intramuscular injection). Other drugs are injected directly into the bloodstream (intravenous injection) providing the most direct route for the systemic administration of the drug. Finally some drugs are injected directly into the blood supply of a specific organ, e.g., the liver or the brain, (intra-arterial injection) to assay the effects of the drug upon that organ. An IV push describes the administration of a "bolus" (a large dose of drug) into a vein with a syringe by a nurse or physician who must apply pressure to the syringe in order to "push" the medication into the vein. An infusion is when the drug is diluted in a bag of fluids and administered over a specified period of time. It may be "dripped" or administered with a pump. The infusion method requires more elaborate preparation, such as pre-mixing and measurement, whereas an injection or push requires filling a syringe with medication.

In 2004 and 2005, the amounts allowed by Medicare and the private payors for the drug administration codes my office utilized most frequently were as follows:

Code	Description	Year	Medicare	Aetna	Health Partners of Philadelphia	Independence Blue Cross
90780	IV infusion for therapy/ diagnosis; up to one hour	2004	$122.65	$45.00	$31.71	$46.00
		2005		$45.00	$31.71	$46.00
G0347	IV infusion for therapy/ diagnosis; up to one hour	2005	$82.79			
90781	IV infusion therapy/ diagnosis; add'l hour	2004	$34.29	$23.00	N/A	$40.00
		2005		$23.00	$31.71	$39.00
G0348	IV infusion therapy/ diagnosis; add'l hour	2005	$27.60			
G0349	IV infusion therapy/ diagnosis; add'l drug	2005	$45.48			
90782	Therapeutic/diagnostic injection; subcutaneous or intramuscular	2004	$25.16	N/A	$4.28	$3.80
		2005		$4.74	N/A	$3.10
G0351	Therapeutic/diagnostic injection	2005	$19.57			
96408	Chemotherapy admin., push technique	2004	$116.00	$40.00	$9.52	$36.00
		2005		$40.00	$9.52	$36.00
G0357	Chemotherapy admin., push technique	2005	$131.05			
G0358	Chemotherapy admin., push technique; add'l drug	2005	$76.21			
96410	Chemotherapy admin., infusion; first hour	2004	$226.08	$63.00	$58.60	$87.00
		2005		$63.00	$58.60	$87.00
G0359	Chemotherapy admin., infusion; first hour	2005	$185.31			
96412	Chemotherapy admin., infusion; add'l hour	2004	$50.56	$47.00	$58.60	$54.00
		2005		$47.00	$58.60	$54.00
G0360	Chemotherapy admin., infusion; add'l hour	2005	$42.13			

While private payors increased reimbursement for drug administration reimbursement slightly in 2004, Medicare significantly increased its reimbursement for drug administration. For example, by looking at the previous chart, one can see that Medicare reimbursement for CPT Code 90780—infusion of saline, an antiemetic, or any other nonchemotherapy drug—increased 187% from $42.72 in 2003 to $122.65 in 2004. Medicare reimbursement for CPT Code 96410—chemotherapy infusion—increased 286% from $58.61 in 2003 to $226.08 in 2004.

In 2005, the drug administration reimbursement for Medicare was higher than 2002 and 2003 but less than 2004. For example, Medicare reimbursement for CPT Code 90780 (replaced by G0347 in 2005) increased 94% from $42.72 in 2003 to $82.79 in 2005. Medicare reimbursement for CPT Code 96410 (replaced by G0359) increased 216% from $58.61 in 2003 to $185.31 in 2005. Although Medicare reimbursement for

drug administration was lower in 2005 than in 2004, Medicare added new temporary drug administration codes that allowed my practice to bill for infusion of additional nonchemotherapy drugs (G0349) and for administration of additional chemotherapy drugs by IV push (G0358). These new codes better reflect the chemotherapy administration expenses my practice incurs in providing chemotherapy treatment to my patients. Because these G codes were temporary one year codes, the private payors did not switch to G codes. Private payors continued using the old CPT codes in 2005.

While these additional G codes are an improvement over the old drug administration codes, Medicare still does not reimburse for all chemotherapy administration services. For instance, it remains the case that if a patient is infused with saline concurrent with infusion of a chemotherapy agent, the hydration cannot be billed separately. If hydration is provided to facilitate drug delivery, it is considered incidental to that infusion and also cannot be billed separately. In addition, my office still cannot bill separately for flushing a patient's vascular access port prior to the administration of the chemotherapy agent.[8] Medicare and private payors consider it part and parcel of the chemotherapy administration.

As the above suggests, billing for drug administration is highly complex and requires both time and expertise on the part of my nurses and office staff that is not adequately accounted for in the reimbursement for the services themselves. My nurses must keep track of the various drug administrations and the time each takes and must properly document this information. My biller must translate this "real-world" information into the Byzantine coding jargon of the payors. Any errors in either the recording of what transpired with the patients or in the bills sent to the payors causes a delay if not a denial in the reimbursement I receive, leaving me uncompensated. Moreover, on occasion, the Medicare carrier and the private payors also make errors on their end and my office must follow-up with payors to get properly reimbursed.

50. *J-Codes*: My office bills Medicare and the health plans for drugs administered to patients using J-Codes. J-Codes describe the molecule and the dosage amount. For a few drugs, the J-Code will correspond directly to a National Drug Code ("NDC") number that would provide an informed reader with the name of the drug's manufacturer, the drug's strength and the package size that it comes in. This will hold either because the drug is so new that it has been assigned its own temporary J-Code or because, during the time it remains on patent, there is no other therapeutic or generic competition. However, many of the drugs I prescribe for patients do have therapeutic or generic competition. All such drugs are grouped under one J-Code regardless of the identity of the manufacturer. For example, the J-Code for carboplatin 50 mg is J9045. Regardless of whether I use Paraplatin, the innovator, brand name drug by Bristol-Myers Squibb Company, or a generic carboplatin manufactured by another company, my office bills that drug as J9045.

[8] A vascular access port is inserted in about 30% of my patients to provide for better access of the patient's vein for drug administration. These patients need a vascular access port either because they have small veins, need repeated frequent chemotherapy administration, or experience a burning sensation when a chemotherapy drug is administered directly in their veins.

The only way to know which manufacturer's drug was actually administered to a patient would be to look at what was in my inventory at that time.

I do not know precisely how Medicare established the amounts it was willing to reimburse for a J-Code drug. I do know that the methodology was, prior to 2005, based in part on Average Wholesale Price or AWP. I also understand that several of my private payors used either the Medicare J-Code amounts or some formula based in part on AWP to reimburse me for the drugs that I provided to their insureds. In many cases (but not all), I was able to acquire drugs for my inventory at prices less than the amounts at which I was reimbursed. This difference between my acquisition cost and the price that I was reimbursed was income for my practice. This drug income was absolutely essential to make up for (1) drug-related expenditures (such as financing, storage, mixing, waste) that were not separately billable, (2) the under-reimbursed and totally unreimbursed services, facilities and supplies I provided through my office and (3) instances where insurers or patients failed to pay me. Without the drug income, it would not have been financially worthwhile for me to have maintained my office-based practice.

I generally acquire drugs through OTN, a specialty distributor. As a member of a group purchasing organization called Pennsylvania Oncology Hematology Managers Society (POHMS), I am able to obtain from OTN more favorable prices for drugs and supplies than I could obtain on my own. To run my practice, I must keep a certain amount of drugs in inventory. This is very expensive because I must pay OTN within 10 days, but I generally am not reimbursed for 45 days, at least. I have to absorb the cost of financing this inventory, which because of the expense of these drugs is considerable. My average monthly spending on drugs purchased from OTN ranged from $59,778 to $153,016 between 2002-2005. In addition, some of the drugs have special storage requirements (such as refrigeration) that I must pay for.

When a patient arrives in my office for drug administration, the prescribed drugs are taken from inventory and are prepared. As noted above, this usually involves mixing toxic substances under a laminar flow hood. There is no CPT Code that covered this service, nor was I separately reimbursed for the building space or the environmental controls I must maintain to provide the service.

Finally, to administer the drug, my office uses gowns, gloves, tubes, needles, gauze, tape and other supplies. None of these indirect costs is separately reimbursed under the CPT Codes; the only way for me to recoup these expenses is as part of the drug reimbursement itself.

Coverage Denials and Patient Co-Payments

51. Medicare Part B patients pay an annual deductible and 20% of the allowed charges for physician services and drugs. The patient is responsible for 20% of the allowed charge for the office visit, administration of drugs, and the drugs. For a patient with private health insurance, the co-pay due for the office visit, administration of drugs and

drugs is usually a flat amount negotiated between the insurer and the patient's plan sponsor.

52. It is important to stress that, even when a patient has Medicare or private insurance and my office does its level best in terms of the complex coding and billing for a patient's treatment, I sometimes lose a substantial amount of money because (1) Medicare or the private payor denies a claim in part or in full and/or (2) I am unable to collect a co-payment owed by the patient. The staff must approach patients at the front desk when they arrive to the scheduled appointment to confirm that the appropriate referral has been obtained and to collect the copayments.

For example, if I want to give my patient an expensive single-source drug because that drug is the best for that patient based on his cancer and overall medical condition, I request my biller to call the health plan to see if the plan will reimburse me at all. Even when I am assured by the payor that an expensive drug will be reimbursed, the claim still may later be denied. I then have to appeal several times with the health plan. If the appeals fails—which happens on occasion—I can lose thousands of dollars for the drug and for the time and effort in pursuing the denial and appeal.

53. This section has attempted to present the reader with a general description of the economics of my practice. In the following section, I use my practice's financial records to display and analyze the revenues and expenses for 2002 and 2003, which are reflective of the methodology prior to the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("Medicare Modernization Act") of using drug revenues through AWP-based reimbursement to subsidize the unreimbursed and under-reimbursed aspects of office-based medical oncology. Thus far, of the payors I work with, only Medicare has moved away from that reimbursement system. 2004 was a "transition" year under the Medicare Modernization Act. In 2005, Medicare reduced the revenues on drugs by reimbursing drugs at ASP +6 %, implemented a "demonstration" project, and increased the payments for office visits under certain CPT Codes and administration of drugs under the new G Codes. I use my practice's financial records to illustrate the effect of the changes in 2004 and 2005.

VII. ECONOMICS OF MY OFFICE PRACTICE: 2002-2005

54. In my office, there are two primary sources of data concerning the revenue and expenses of my practice. The first is "Explanation of Benefit" forms ("EOBs") from Medicare and private payors, which accompany reimbursement checks and describe in detail the revenue that my practice receives.[9] The second source is data from a simple commercially available software program called "Quickbooks," which is used in my office to track revenue and expenses. Sometimes, I retain the actual "hardcopy" of

[9] An Explanation of Benefits (EOB) is a notification form that a health plan sends my office and the patient after processing the claims my office billed. This form includes the services and drugs billed by my office, the amounts allowed and paid, the patient's deductible, and the patient's copayment amount owed to my office.

statements or invoices that reflect my expenses, but I believe that Quickbooks is more complete. I routinely purchase drugs and certain other supplies through OTN. Because OTN is a defendant in this case, it was willing to search its own records for a history of my purchases. The OTN data is more complete than my own records and the financial analysis in this section of my report relies on the OTN data whenever possible.

55. At the request of the Track 1 defendants, I have turned over my EOBs, Quickbooks data, hardcopy invoices and OTN data for the years 2002-2005 (inclusive) to employees of CRA International ("CRA"), whom I understand also to be an expert witness upon whom the defendants are relying. I have made myself and my office staff available to CRA staff to answer questions they may have about the information. CRA, not I, created the exhibits that follow concerning the finances of my practice based on the above information. However, I have reviewed the exhibits thoroughly and, based on my own first-hand experience in running my practice, I believe that the results accurately reflect my revenue and expenses and my income and losses. The purpose of this section of my report is to elaborate on CRA's findings, especially those concerning the relationship over time between revenues/expenses related to the drugs I prescribe versus the revenues/expenses related to all other parts of my practice. I conclude that the income from the drugs has historically subsidized losses on my services and other expenses.

56. Below, at Exhibit 1, is CRA's analysis of my practice's financial records from 2002-2005. For 2005, CRA analyzed only the revenues and expenses from January through September because not all of the information for the last months of 2005 was available when this report was written. However, CRA has extrapolated and computed the last quarter based on the first three quarters' results in order to permit a comparison of all years from 2002 to 2005 on an annualized basis.

57. Among the payors with whom I worked in the period under analysis, only Medicare has switched from a reimbursement mechanism for drugs based on AWP to one based on ASPs. As I discuss below, the impact of this change is clear: I am no longer making significant margins under Medicare on most drugs and, in fact, I am in some cases losing money providing Medicare patients with new classes of drugs. The effect on my practice has been somewhat ameliorated by the fact that I have a fairly low number of Medicare patients as a percentage of the total patient/payor mix.

Exhibit 1

Physician Oncology, LTD

2002-2005 Income Statements, Accrual Method
By Source of Payment (Third-Party Payor and Patient)

	Revenues	2002 [a]	2003 [b]	2004 [c]	2005 [d]
	Amount Paid by Public and Private Third-Party Payors				
[1]	Amount Paid for Drugs	$971,685	$967,086	$1,378,590	$2,242,267
[2]	Amount Paid for Services	$276,974	$218,092	$438,085	$442,000
[3]	Amount Paid for Oncology Demonstration Project	$0	$0	$0	$18,251
	Other Amounts Paid	$54,622	$56,318	$49,883	$34,203
	Total Revenue from Third-Party Payors	$1,303,281	$1,341,497	$1,867,198	$2,736,707
	Amount Designated as Due from Patients				
	Gross Revenue Due from Patients	$227,692	$53,563	$184,788	$125,550
	Uncollected Patient Obligations	($215,882)	($34,470)	($175,607)	($103,184)
	Total Net Revenue from Patients	$11,810	$17,093	$10,156	$21,366
	Total Net Revenue	$1,255,091	$1,358,592	$1,877,354	$2,758,073
	Costs and Expenses				
	OTN Drug Purchases	$730,014	$842,302	$989,301	$1,947,768
	Rebates and Discounts	($32,681)	($2,819)	($20,204)	($111,397)
[4]	Medical Supplies	$24,517	$21,421	$20,674	$26,973
	Office Supplies	$12,718	$11,739	$7,309	$16,093
	Payroll and Payroll Taxes excluding physician's salary	$164,975	$143,574	$134,244	$228,975
	Employee Health Insurance	$7,296	$7,153	$12,349	$30,533
	Rent	$34,854	$34,425	$74,073	$68,588
[5]	Other	$50,732	$111,103	$133,515	$150,286
	Total Costs and Expenses	$1,055,924	$1,197,899	$1,351,462	$2,361,567
	Net Income (including Physician's Salary)	$199,166	$160,307	$525,892	$416,506

[1] EOB payments received from third-party payors for HCPCS J-Codes, Q0136, S5000, S5001, and 90725
[2] EOB payments for all Service-Related billing codes
[3] EOB payments received from third-party payors, including Medigap, for Oncology Demonstration Project Codes
[4] [a] Medical Supply expenses as recorded on Dr. Linda Hargele's QuickBooks accounts
[4] [b-d] Medical Supply expenses paid to specifically identified suppliers other than OTN as recorded on Dr. Linda Hargele's QuickBooks accounts plus OTN purchases of medical supplies
[5] Expenses categorized as advertising and promotion, amortization, automobile, bank fees, charity, depreciation, dues and licenses, entertainment, gifts, malpractice insurance, group and liability insurance, interest, legal, meetings and education, miscellaneous, outside services, patient relations, payroll service fees, postage, professional fees, refunds, repairs and maintenance, subscriptions and books, other taxes, telephone, travel, uniforms, utilities, and waste removal expenses per QuickBooks accounts
[d] Annualized based on data from the first three quarters of 2005

58. CRA created the income statements in Exhibit 1 by analyzing the revenues (a) from payors for (i) drugs and (ii) services (i.e. office visits, lab work and administration of services) and (b) the amounts due from patients (without a breakdown as between drugs and services). The total revenues were adjusted to reflect the write-off of the uncollected patient co-pays, which were quite substantial. Losses due to drug coverage denial by payors are reflected as an expense (for my purchase of the drug) without any offsetting revenue (since the EOB would reflect no payment for the drug by the payor).[10] CRA also analyzed the expenses incurred by my practice including OTN drug purchases

[10] My practice incurred bad debt for several reasons. Sometimes, I and my staff were unable to collect the co-pay from patients. Other times, my practice treated patients who appeared to have insurance coverage, but whose coverage had in fact lapsed and whose claims were denied by the insurance companies on that basis. Finally, as I noted above, some insurers have denied coverage for some drugs even after my practice had been told orally, in a prior-authorization phone call, that the drugs would be covered by them.

(less drug rebates and discounts), medical supplies, office supplies, staff payroll and payroll taxes, employee health insurance, rent and other expenses. These other expenses include advertising and promotion, amortization, automobile, bank fees, charity, depreciation, dues and licenses, professional fees, entertainment, gifts, malpractice insurance, group and liability insurance, interest, meetings and education, payroll service fees, postage, refunds, repairs and maintenance, subscriptions and books, telephone, travel, uniforms, utilities, waste removal expenses and taxes.

59. As one can see from Exhibit 1, my net income during the course of the year has ranged from $200,000 to $416,000 per year, with one year (2003) reflecting a loss. I believe that these amounts are on the low end of the range for medical oncologists in the Greater Philadelphia area and are very low compared to other private-sector professionals given the relative time, expense and effort I put into my education, training and day-to-day practice. My income reflects my personal commitment to serving people from all walks of life.

60. Uncollected patient obligations are a significant drain on my practice, although I cannot blame my loss in 2003 entirely on that issue. For example, in 2002, my practice wrote off $215,882 in bad debt as a result of uncollected patient copays, lapsed coverage, and drug coverage denial. $161,135 was attributable to one patient. His health plan denied coverage of an expensive drug that I administered to him despite what I believe was a prior approval by the plan. The patient passed away in late 2002 and I never was able to collect the debt. It should be noted that some of the bad debt in 2005 resulted from my decision not to ask my patients for co-payments relating to Medicare's "oncology demonstration project." I felt it was hard enough for my patients to pay their share of services and drugs without adding to their financial burden by asking for a co-pay on the demonstration projection. [11]

61. I lost money in 2003 primarily because I had an inexperienced biller. Exhibit 1 shows that while my drug expenses increased from 2002 to 2003, I received much less revenue from third-party payors and, particularly, from patients. My biller also did not call the health plans to see if the patients had current insurance coverage before we treated them. As a result, I treated a number of patients who had no insurance. My biller also failed to follow up on denials of claim when there was coverage. In many cases, my office did not even try to obtain payment from the patients, thus explaining why both the gross revenue due from patients and uncollected patient obligations are so low for 2003.

[11] The oncology demonstration project focused on three areas of concern often raised by patients undergoing chemotherapy: controlling pain; minimizing nausea and vomiting; and reducing fatigue. To participate in the demonstration project, the nurse fills out a questionnaire that asks the Medicare patient questions about his or her symptoms and quality of life during the course of chemotherapy administration. My practice is reimbursed $130 per Medicare patient per encounter for participating in the nationwide demonstration project. The oncology demonstration project can only be billed in conjunction with either G0357 (chemotherapy administered through intravenous push) or G0359 (chemotherapy administered through infusion).

62. Exhibit 1 also shows that in every year from 2002 to 2005, the revenue that I received from payors relating to the drugs I administer is much higher as a percentage of total revenue than the revenue I receive from services. This is especially true in the period 2002-2003 – before the effect of the Medicare Modernization Act. The relationship between drug and other revenues started to change beginning in 2004.[12] I explore this change further in Exhibit 2 below.

63. Exhibit 2 contains the exact same raw data as Exhibit 1, but allocates expenses related to drug revenues separately from expenses related to services revenue in order to show my practice's operating profit (or loss) from drugs versus services. CRA calculated the drug revenues by analyzing the amount reimbursed by Medicare and private payors for the drugs plus the amount of co-pay for the drug due from the patient minus the cost of my drug purchases from OTN (accounting for any rebates or discounts I received) and minus the bad debt written off as a result of uncollected patient drug co-pays. As the reader can see, even with the bad debt and denials by payors, I have in every year operated at a profit on the drugs themselves.

64. CRA analyzed the service revenues from office visits, lab work and drug administration by determining the amount reimbursed by Medicare and private payors and patient co-pays less all expenses not included in the drug expenses: medical supplies, office supplies, staff payroll expenses, staff health insurance, rent, and other expenses described above. As the reader will see, I broke even or lost money on the "services" side of my practice in 2002 and 2003 (before the Medicare Modernization Act) and only made money once Medicare began changing the reimbursement for services in 2004. I would also have done well on services in 2005 had I not experienced a large increase in the payroll and payroll taxes relative to 2004. My payroll and taxes went up because my per diem nurses worked more hours, I employed a full-time biller for the entire year and I retained a consultant to help me with my practice management.

[12] For 2002 and 2003, Medicare set drug reimbursement at the lower of the billed charge for a drug or 95% of a drug's AWP. In 2004, Medicare increased its payments for office visits and drug administration services and decreased payments for drugs by reimbursing at 85% of a drug's AWP (as of April 1, 2003) or 95% of a new drug's AWP. A new drug is defined as an unlisted drug, not covered by a HCPCS code, that was FDA-approved after April 1, 2003.

Exhibit 2
Physician Oncology, LTD
2002-2005 Income Statements, Accrual Method
By Source of Revenue (Drug Revenue versus Procedure Revenue)

		2002	2003	2004	2005
		[a]	[b]	[c]	[d]
[1]	**Drug Revenue**				
	Amount Paid by Third-Party Payors for Drugs	$971,685	$867,085	$1,378,390	$2,242,287
	Amount Due from Patients for Drugs less Medigap payments	$129,678	$16,687	$112,944	$58,828
[2]	Patient Obligation 'Write-Offs' of Drug Revenue	($189,677)	($16,687)	($112,944)	($59,828)
	Total Net Revenue from Drugs	$911,685	$867,085	$1,378,390	$2,242,287
	OTN Drug Purchases	$750,814	$642,502	$969,501	$1,947,744
	Rebates and Discounts	($32,682)	($2,819)	($59,264)	($111,571)
	Total Net Drug-Related Costs	$717,254	$639,682	$969,096	$1,836,197
	Operating Profit from Drugs	$194,361	$227,404	$409,234	$406,079
	Operating Margin from Drugs	21.3%	32%	17.8%	18.1%
[3]	**Service-Related, Oncology Demonstration Project, and Other Revenues**				
	Amount Paid by Third-Party Payors for Services	$276,978	$218,692	$458,885	$442,600
	Amount Due from Patients for Services less Medigap payments	$55,443	$29,909	$73,869	$42,560
	Other Amounts Due from Patients less Medigap payments	$2,578	$4,963	$2,250	$451
	Amount Due from Patients for Demonstration Project less Medigap payments	$0	$0	$0	$3,171
	Amount Paid by Medicare for Demonstration Project	$0	$0	$0	$18,271
	Other Amounts Paid by Third-Party Payors	$54,422	$55,318	$49,885	$34,188
[4]	Patient Obligation 'Write-Offs' of Service-Related, Demonstration Project, and Other Revenue	($26,210)	($18,773)	($67,665)	($42,756)
	Total Net Service-Related, Oncology Demonstration Project, and Other Revenue	$343,456	$291,505	$519,326	$518,405
	Expenses				
[5]	Medical Supplies	$24,519	$25,426	$20,876	$25,973
	Office Supplies	$12,718	$11,739	$7,309	$16,098
	Payroll and Payroll Taxes excluding physician's salary	$164,975	$168,574	$134,266	$230,976
	Employee Health Insurance	$7,296	$2,155	$22,369	$30,538
	Rent	$38,354	$58,425	$74,073	$64,538
[6]	Other	$90,350	$111,109	$109,313	$130,286
	Total Service-Related and Other Expenses	$338,591	$360,427	$367,946	$505,649
	Operating Profit from Service-Related, Demonstration Project, and Other Revenue	$4,815	($69,971)	$151,358	$10,356
	Operating Margin from Service-Related, Demonstration Project, and Other Revenue	1.4%	-20.9%	22.9%	2.0%
	Net Income (including Physician's Salary)	$199,166	($33,307)	$323,592	$421,416
	Total Operating Margin	25.9%	-2.9%	29.2%	25.2%

[1] EOB revenue from HCPCS J-Codes, Q0138, S5400, S5817, and S0023
[2] Amounts due from patients for Drugs less allocated amounts paid by patients and Medigap plans
[3] EOB revenue from Service-Related, Oncology Demonstration Project, and Other billing codes
[4] Amounts due from patients for Service-Related, Oncology Demonstration Project, and Other billing codes less allocated amounts paid by patients and Medigap plans
[5] [a] Medical Supply expenses as recorded on Dr. Linda Hengle's QuickBooks accounts
[5] [b-d] Medical Supply expenses paid to specifically identified suppliers other than OTN as recorded on Dr. Linda Hengle's QuickBooks accounts plus OTN purchases of medical supplies
[6] Expenses categorized as advertising and promotion, association, automobile, bank fees, charity, depreciation, dues and licenses, entertainment, equipment rentals, gifts, malpractice insurance, group and liability insurance, interest, legal, meetings and education, miscellaneous, outside services, patient relations, payroll service fees, postage, professional fees, refunds, repairs and maintenance, subscriptions and books, other taxes, telephone, travel, uniforms, utilities, and waste removal expenses per QuickBooks accounts
[d] Annualized based on data from the first three quarters of 2005

65. There were other important changes to my practice from 2004 to 2005. First, both my drug revenues and expenses increased dramatically compared to prior years. As I explain more fully below, this is in part because of the availability of new and improved drugs with which to treat cancer. Second, as already noted, in 2005, Medicare began reimbursing for drugs based on ASP + 6%. Fortunately, none of the private payors with whom I worked followed Medicare's lead. Americhoice and Aetna US Healthcare reimbursed drugs at 85% of AWP. Independent Blue Cross reimbursed at 90% of AWP. Health Partners of Philadelphia reimbursed at 85% of AWP. After discussing the reasons for the changes in my drug prescribing patterns, I will attempt to demonstrate for the

reader the implications for patient care in Medicare's change to an ASP reimbursement methodology. In brief, I am making less— and in some cases losing money— on the drugs that I administer to Medicare patients.

66. Some of the relatively new drugs that I have begun to use include Avastin, Herceptin and Erbitux. These drugs are part of what is referred to as "targeted therapies." In the past, many cytotoxic chemotherapy drugs indiscriminately killed not only cancer cells but also rapidly dividing normal cells such as bone marrow, causing side-effects like neutropenia. These new drugs differ from the older cytotoxic drugs because they are developed utilizing the biochemistry of the tumor. Because tumors produce certain proteins that normal cells do not have, the drug can target and attack the cancer cells without damaging normal cells. This leads to fewer adverse side-effects for patients. These drugs are expensive because of the high research and development costs and extensive clinical trials. While I believe that these new drugs are better for my patients than some of the older drugs, I make sure I get pre-certification because I cannot afford to have a claim denied.

67. During 2005, I also made a shift in the erythropoietin that I prescribed for many of my patients from Procrit to Aranesp.[13] In my professional opinion Aranesp is equally effective as Procrit, but Aranesp saves me and my patients time. Moreover, it was not financially feasible for me to provide Procit to Medicare patients in 2005 because the Medicare reimbursement did not cover my acquisition cost. My practice lost $71.53 per shot of Procrit administered to Medicare patients.

68. Beginning in 2005, I started prescribing many patients Neulasta instead of Neupogen. Both drugs are colony-stimulating growth factors that stimulate the bone marrow to make white blood cells to fight chemotherapy-induced neutropenia. In my opinion, Neulasta is as effective as Neupogen, but is much more convenient for my patients than Neupogen. While Neupogen must be administered daily, Neulasta may be administered as a single dose per chemotherapy cycle. This results in fewer injections and fewer office visits for my patients.

69. Below, Exhibit 3 shows the margins I received on all drugs administered to Medicare patients in both 2004 and 2005. Significantly, Medicare's reimbursement of 85% of AWP in 2004 did not cover my acquisition cost for the following drugs: Zometa, fluorouracil, RituXan, Herceptin, and Faslodex. In other words, I lost money on these drugs when I prescribed them for my Medicare patients. Unfortunately, Medicare's switch to a reimbursement of ASP + 6% in 2005 exacerbated the problem. In 2005, the Medicare reimbursement for almost half of the drugs I prescribed did not compensate me fully for the drugs' acquisition cost. I was unable to recover the cost of the following drugs: leucovorin calcium, diphenhydramine HCL, normal saline solution, cyclophosphamide, fluorouracil, RituXan, Herceptin, Faslodex, and Procrit. I do not believe that I will be able to continue to afford providing the best drugs to my Medicare

[13] Erythropoietin, a growth factor, is administered to increase a patient's red blood count during the course of chemotherapy treatment.

patients unless Medicare significantly improves the compensation for my services and practice expenses.

Exhibit 3
Physician Oncology, LTD
Medicare Drug Margins, 2004 - 2005

2004 - 2005 Summary

Drug Name	HCPCS Code	2004 Net Cost per Billing Unit	2004 Medicare Reimbursement Amount	2004 Gross Margin (%)[1]	2005 Net Cost per Billing Unit	2005 Medicare Reimbursement Amount	2005 Gross Margin (%)[1]	Change in Gross Margin %
Leucovorin calcium	J0640	$1.18	$2.83	58.5%	$2.09	$1.21	-72.6%	-131.2%
Darbepoetin alfa (Aranesp)	J0880	$18.81	$20.14	10.8%	$24.24	$13.31	7.0%	-3.6%
Dexamethasone sodium phosphate	J1100	$0.06	$0.10	44.0%	$0.06	$0.16	60.1%	16.1%
Diphenhydramine HCl	J1200	$0.98	$1.36	27.8%	$0.99	$0.55	-80.1%	-107.9%
Dolasetron mesylate (Anzemet)	J1260	$3.05	$13.16	61.8%	$3.98	$6.11	34.8%	-27.0%
Fondiparinux sodium	J1650	$71.15	$225.99	68.5%	$51.98	$54.48	4.6%	-63.9%
Pegfilgrastim (Neulasta)	J2505	$2,299.24	$2,382.13	3.5%	$1,929.62	$2,160.29	10.7%	5.3%
Zoledronic acid (Zometa)	J3487	$1,89.20	$184.81	-2.3%	$187.96	$198.78	0.6%	2.8%
Normal saline solution	J7050	$0.89	$2.11	57.6%	$0.93	$0.26	-296.2%	-353.8%
Carboplatin	J9045	$47.34	$128.59	51.6%	$24.64	$119.20	87.5%	36.3%
Cyclophosphamide	J9070	$2.13	$4.87	56.8%	$1.81	$3.81	-0.1%	-56.8%
Docetaxel (Taxotere)	J9170	$278.64	$286.33	2.7%	$268.38	$280.91	4.5%	1.8%
Fluorouracil	J9190	$1.85	$1.76	-5.1%	$1.81	$1.76	-3.1%	1.9%
Methotrexate sodium	J9250	$2.11	$6.04	67.7%	$2.11	$2.58	16.4%	-31.3%
Rituximab (RituXan)	J9310	$480.02	$416.46	-3.3%	$457.38	$455.12	-1.0%	2.3%
Trastuzumab (Herceptin)	J9355	$50.50	$49.41	-2.2%	$52.71	$50.38	-3.7%	-1.5%
Vinorelbine tartrate	J9390	$43.17	$72.58	40.4%	$34.05	$58.61	41.9%	1.6%
Fluvestrant (Faslodex)	J9395	$78.62	$77.49	-1.5%	$79.05	$77.33	-2.2%	-0.8%
Epoetin alfa (Procrit)	Q0136	$8.61	$11.04	22.0%	$11.10	$9.32	-19.2%	-41.2%

1: Gross Margin (%) equals Reimbursement Amount minus Net Cost per Billing Unit divided by Reimbursement Amount.
2: Excludes losses on refunds for returned Epoetin alfa in 2005

70. The problem is even more acute for an oncologist with a higher percentage Medicare patient mix than mine. While I have a Medicare Part B patient mix of 15-20%, many medical oncology practices have a Medicare patient mix of 50%. The data suggest such office-based oncologists would not be able to treat their Medicare Part B patients without significant increases in reimbursements for services.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO: ALL CLASS ACTIONS	Judge Patti B. Saris

REPORT OF E.M. (MICK) KOLASSA, PH.D

March 21, 2006

Introduction

Dr. Kolassa is the Managing Partner of Medical Marketing Economics, LLC. Dr. Kolassa is also an Adjunct Associate Professor of Pharmacy Administration in the School of Pharmacy at the University of Mississippi. Dr. Kolassa is the author of *The Elements of Pharmaceutical Pricing*. Attached as Exhibit A is a current Resume of Dr. Kolassa which lists his previous positions in the area of pharmaceutical economics, his professional associations, and the numerous publications authored by Dr. Kolassa. Dr. Kolassa has served as an advisor to various governmental departments and agencies concerning drug pricing issues including the United States Department of Health and Human Services, United States HealthCare Finance Administration, CMS, Food and Drug Administration, Federal Bureau of Investigation and Mississippi Medicaid.

Prior Testimony

My curriculum vita is appended to this report as Exhibit 1. This includes a list of my testimony as an expert witness at trial or by deposition within the last four years.

Publications

My curriculum vita is appended to this report as Exhibit 1. This includes a list of all publications I have authored within the preceding ten years.

Assignment

Counsel for Schering-Plough Corporation, Schering Corporation and Warrick Pharmaceuticals Corporation asked me to analyze and explain the economic issues raised by the claims asserted by the plaintiffs. In addition, I have been asked to explain the basic principles of pharmaceutical marketing and economics. Finally, I have been asked to comment upon the expert opinions offered by Drs. Hartman and Rosenthal. Specifically, I have been asked to address how both Drs. Hartman and Rosenthal fail to address and account for the "real world" of pharmaceutical marketing and economics.

Materials reviewed and relied upon

In preparing this report, I have reviewed and relied upon information from a number of sources. These include documents produced in the litigation, information from publicly available sources, depositions, and discussions with Warrick and Schering personnel. In addition, I have relied upon my extensive study of the pharmaceutical industry and Medicaid reimbursement programs during my career in pharmaceutical marketing and economics spanning more than 25 years.

Compensation

For my services in this matter, Schering-Plough and Warrick are compensating me at $750.00 per hour.

General subject areas of opinions

In giving my opinions, I expect to testify on the following general subject matters.

a. Pharmaceutical economics.

b. The pharmaceutical marketplace.

c. The importance of innovator generic drugs as a factor in creating and maintaining market share.

d. Pharmaceutical pricing.

e. The definitions, understanding and calculation of prices using the various pharmaceutical pricing terms.

f. The manner in which drug manufacturers determine, report and calculate prices for pharmaceuticals.

g. Information available to Medicaid and Medicare programs that enables them to estimate the actual acquisition cost of prescription drugs.

h. The government's knowledge of pharmaceutical prices reported by drug manufacturers and others.

i. Price and cost reporting mechanisms in the pharmaceutical marketplace.

j. The use of pricing terminology within the pharmaceutical marketplace.

k. Price setting, reporting, and publishing by drug manufacturers.

l. Price reporting and publishing by third-party price publishing services.

m. The role of price publishing services in the pharmaceutical marketplace and their relationship to Medicaid and Medicare reimbursement.

n. The environment in which pharmaceutical prices are negotiated, set, calculated and reported.

o. Pharmaceutical reimbursement

p. Health care public policy as it relates to pharmaceuticals, pharmaceutical economics, and pharmaceutical reimbursement.

q. The differences between brand and generic pharmaceutical pricing and reimbursement policy and the manner in which private third party payers use varying formulas for reimbursement of brands and generics.

r. The factors that drive pharmaceutical buying decisions, including the fact that generic reimbursement spreads do not drive such purchasing decisions nor do they cause or account for the Defendants' market shares in the Relevant Drugs.

s. The procedures and policies utilized by third party payers to incentivize the use of generic rather than brand drugs and how the utilization of generics reduces the overall cost of drugs.

t. How MAC's are and should be utilized to control the cost of pharmaceutical reimbursement.

u. The knowledge of DEMERCs and their ability to suggest or set a MAC.

v. How participants in the health care system have lobbied for policies fair and equitable to their respective concerns.

w. Why Medicaid and Medicare have greatly benefited from generic competition and lower generic prices.

x. The Medicare and Medicaid Programs' policies and procedures for reimbursing for pharmaceuticals, currently and historically.

y. How various state Medicaid Programs have controlled their reimbursement for pharmaceuticals.

z. The Medicaid Rebate Program.

aa. State and federal efforts to estimate drug acquisition cost in making pharmacy reimbursement decisions.

bb. Policy reasons behind the reimbursement decisions made by Medicare and Medicaid programs.

cc. The public policies associated with Medicare and Medicaid reimbursement.

dd. The lack of causation between the alleged acts of the Defendants and the damages claimed by the Plaintiffs.

ee. An analysis of the alleged damages claimed by the Plaintiffs.

ff. I will also review and evaluate the analysis in this matter performed by Plaintiffs' experts including any subject matters or topics that are the subject of his opinions.

gg. I will rebut the opinions of Plaintiffs' experts where appropriate.

General opinions

The general substance of my mental impressions and opinions and a brief summary of their bases are:

a. AWP, as a sticker, reference or benchmark price, does not generally purport to be an actual price to any segment of the pharmaceutical market. It is not and has not been understood to be an actual price. It is not an "average" of actual prices nor is it a price at which pharmacies buy from wholesalers.

b. AWP for generic products can vary by manufacturer but is typically set at the launch of the product at least 10% below the AWP price of a therapeutically equivalent branded product. Historically, once set, AWP typically is not reduced.

c. AWP prices are neither "true" nor "false." They are simply a benchmark or reference price from which other reimbursement rates are determined by a third party payor. The third party payor chooses how much and when to discount off of AWP. AWP is not understood to be reflective of actual price transactions.

d. For decades the pharmaceutical industry and government regulators have known that AWP is generally significantly higher than actual pharmaceutical contract prices in the marketplace.

e. The federal government has failed to publish any meaningful definition of its pricing terms used for reimbursement during the relevant time period of the claims asserted. There are no state or federal laws or regulations as to when or how an AWP should be published, whether it must be published and/or when it should be adjusted, changed or updated.

f. Government authorities have had reason to be aware of the fact that discounts off of AWP are available in the marketplace, and in fact have sources of information indicating the existence of discounted pricing available to them.

g. WAC is a well-understood industry term meaning the manufacturer's invoice price to wholesalers, essentially a list price.

h. WAC, as a list price, does not purport to reflect special deal terms, discounts, rebates, or chargebacks to wholesalers or other classes of trade in the pharmaceutical industry.

i. There is no state or federal law or regulation that requires Medicaid programs to actually use AWP as a method to establish reimbursement rates.

j. To the extent that Medicare used AWP or WAC in their reimbursement formulas, Defendants did not cause the alleged damages asserted by the Plaintiffs and their experts.

k. So-called "spread" is a factor that contributes to providers' gross margins, a concept essential to profitability in sales industries. Government regulators generally know there is a "spread" and, in fact, create and allow such spreads to be paid to providers to cover their costs and insure access to the various programs. Spreads vary significantly for generic drugs, and there is no uniform "expectation" in the marketplace as to specific amounts of spread.

l. Given the nature of Medicaid, Medicare and private payor reimbursement, the existence of an adequate profit margin for providers is essential if generic products are to be introduced or survive against their branded counterparts in a competitive market. This furthers valid policies by encouraging the dispensation of generic drugs and overall cost savings.

m. Given that participation in government programs by providers is voluntary and yet essential if the goal of providing necessary medications to patients is to be realized, an adequate profit margin must be part of the reimbursement process and is indispensable to assure access to medications.

n. The dispensing of generic drugs operates to reduce overall costs of healthcare, over time, because such drugs are less expensive than their branded counterparts and thus drive down overall costs through price competition.

o. The Medicaid and Medicare reimbursement systems have not purported to capture the variability of drug price discounts negotiated in the marketplace.

p. The failure of Medicaid and Medicare authorities to adopt a practice of using fully discounted contract prices in their formula reflects their policy to use the product ingredient cost as a compensatory component of the reimbursement to subsidize pharmacies to assure their continued voluntary participation in the Medicaid and Medicare programs.

q. Medicaid and Medicare authorities have not used actual acquisition costs as a measure of product reimbursement.

r. As between a manufacturer, a wholesaler and a retail pharmacy, the pharmaceutical manufacturer is least able to estimate the pharmacy's actual acquisition cost.

s. Contract prices are not standardized in the pharmaceutical industry but are variable depending, among other things, on the leverage of the purchaser or its representative, the buying relationship, the nature of the purchase transaction, and the extent and volume of the products purchased over time.

t. The manufacturer's contracts with its customers reflect post-market deal terms that are often not known or knowable at the time the product is initially sold.

u. AMP represents an average manufacturer's price reflecting the effect of certain deal terms negotiated in the marketplace, such as discounts, rebates, and

chargebacks. WAC and AMP are pricing concepts distinct and different from AWP.

v. Actual contract prices can be so numerous that updating them in reports to Medicaid authorities on each generic product would be a continuous and unrealistically onerous exercise for a manufacturer or regulatory entity.

w. AMP can easily be approximated from the generic manufacturer's OBRA-mandated rebate or publicly available VA prices.

x. State and federal regulators control the amount of reimbursements to be paid, not the pharmaceutical companies.

y. After Medicare began utilizing ASP as the basis of reimbursement, it implemented a substantial dispending fee for albuterol. This increase oftentimes results in cost increases to Medicare (and to the patient).

z. Medicaid and Medicare programs could have used IMS data rather than AWP data from First Databank. If the programs would have utilized IMS data, they would have been able to better estimate the actual acquisition cost by a retail pharmacy.

aa. I will also address (i) the dynamics, variability, and conventions of the drug purchasing process, including factors such as generic product differentiation and generic product and pricing competition, (ii) the economics of the pharmaceutical industry, including gross and net margins of pharmacies generally and as they relate to reimbursement issues, and (iii) public and political policies impinging on and constraining Medicaid and Medicare reimbursement practices, including necessary provider participation and patient access.

bb. I will explain the structure of the pharmaceutical industry including, without limitation, Defendants' sales methods, channels of distribution and structure operation and control of governmental reimbursement systems.

cc. Wholesaler chargebacks, rebates, allowances, performance incentives and adjustments are different in their natures, purposes, calculations and effects on business. Many of these adjustments and incentives are calculated and awarded long after sales have occurred, making their immediate reporting impossible and their precise effects incalculable.

dd. Federal and state government programs have long known prices in pharmaceutical publishing services do not reflect actual transaction prices. Nearly all of these programs obtain their pricing information from persons or entities other than the drug manufacturers.

ee. None of the Defendants gained or maintained market share as a result of fraudulent activities or practices.

ff. I will also offer opinions rebutting those of the Plaintiffs' expert witnesses where appropriate.

gg. My opinions are based on my extensive study of the pharmaceutical industry and Medicaid reimbursement programs during my career spanning more than 25 years, my review of depositions, pleadings, data and other evidence furnished in connection with this case, and my review of the opinions presented by the Plaintiffs' experts

hh. The bases for of my impressions and opinions are the documents reviewed by me in this litigation as well as my years of education and experience in the pharmaceutical industry.

E M Kolassa

E.M. (Mick) Kolassa

3/21/06

Date

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	Judge Patti B. Saris

MERITS REPORT AND DECLARATION OF FIONA SCOTT MORTON, PH.D.

March 22, 2006

patients.[231] Knowledge by the payor that it is offering large spreads to physicians for a particular purpose would indicate legitimate economic behavior rather than fraud.

2. Payors may use spreads to cross-subsidize other services

139. Payors have incentives to allow physicians to have a spread on drug purchases to compensate for inadequate drug administration fees[232, 233, 234] and substantial practice expenses[235] that are otherwise unreimbursed. Note that the gross revenues associated with the spread are not net profit for the physician to the extent that they are used to compensate for inadequate drug administration fees and for covering

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[231] Holcombe, Dawn, *The Evolution of Community Oncology Care and its Threatened Extinction Due to Federal and Private Payment Reform*, Medical Group Management Association, Aug. 25, 2003 ("Holcombe, 2003"), p. 5: "The chemotherapy DRG – DRG 410 – ended up being the lowest weighted of all DRGs. Inpatient treatment that would have been appropriately paid under the old system was now being paid at an artificially set level intended solely to lower Medicare costs, and thus forced chemotherapy on an inpatient basis to become a loss to hospitals. Tens of thousands of cancer patients were forced to have their care shifted from the inpatient to the outpatient setting, thus also forcing these sick, debilitated and nauseous patients to endure daily travel to receive their care." See, also, Herzlinger, 2002, p. 7.

[232] Prior to [1992], many Medicare carriers allowed a separate payment for chemotherapy administration in the non-office setting in addition to the visit charge…Beginning in 1992, however, HCFA took the position that the chemotherapy administration codes were intended to cover only the technical aspects of the administration and that all physician services were considered to be included in a visit or consultation code. First, because of the unusual amount of work outside the face-to-face encounter, the usual visit codes, which do not explicitly consider such factors in determining the appropriate level of service, may understate the amount of work involved. Second, some carriers continue to apply arbitrary rules limiting use of the higher levels of service of the visit codes, thus precluding their availability as a practical matter." Bailes, Joseph S., "Payment and Coverage Issues Affecting Medical Oncology," *Breast Cancer Research and Treatment*, Vol. 25, 1993, pp. 119–126 at 121–122.

[233] "As we have gathered information on many of the drugs reviewed by DOJ, we have concluded that Medicare payments for services related to the provision of chemotherapy drugs and clotting factors used to treat hemophilia and similar disorders are inadequate." DeParle Letter to Carriers, at AWP041-0945.

[234] Letter from members of Congress to Shalala, 2000, p. 1.

[235] Holcombe, 2003, p. 6. See, also, 53 Fed. Reg. 39644 (October 11, 1988): "Changes in treatment methods and advances in technology now allow chemotherapy to be furnished to many patients in the physician's office, thus reducing the need for hospitalization to administer chemotherapy. Furnishing these services in the physician's office is more convenient for some patients and may provide other benefits as well. Current Medicare Part B payment rules for physicians' services, however, may fail to compensate adequately for these services because the usual reasonable charge methodology may not fully recognize the overhead costs involved in these procedures. Some sources of additional costs include employment of nurse oncologists, special patient rooms, and safety equipment required because of the toxicity of the chemotherapeutic agents and safety procedures issued by the Occupational Safety and Health Administration."

legitimate practice expenses. Such cross-subsidization occurs in the Medicare Part B program for oncologists[236, 237] and other office-based specialist physicians.[238] It is also well documented that private payors use spreads to cross-subsidize other insufficiently reimbursed services, such as drug administration fees and physician practice expenses.[239, 240] Clearly, if payors purposefully allow spreads in order to keep physicians in business, there is no fraud.

3. Payors may use higher spreads on some drugs to offset lower spreads on other drugs

140. As I discuss above, publicly available reports have documented that spreads vary across drugs, and health plan deponents in this matter have acknowledged that providers have positive margins on some drugs and lose money on others.[241] However, since payors focus on the total payments to providers, the variation in margins across individual elements of the fee schedule does not hinder their determination of reimbursement rates. Note that since payors allow margins to vary across drugs and providers' price concessions may vary across drugs, spreads for

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[236] "The components [of Medicare office-based chemotherapy administration] that reflect overhead and other practice expenses, however, are based not on the actual costs incurred by oncologists in providing chemotherapy, but on historically allowed charges. As a result of this approach, Medicare payments for chemotherapy administration appear to be inadequate to cover the costs involved. A pilot study of a few practices conducted by the American Society of Clinical Oncology indicated that many oncologists may be losing money in providing office-based chemotherapy." Bailes, Joseph S., "Reimbursement: Current Status and Future Outlook," *Seminars in Oncology*, Vol. 21, No. 4, Suppl. 7, August 1994, pp. 118–122 at 118.

[237] 2003 MedPAC Report, p. 159.

[238] Medicare reimbursement "for injectable drugs involves what has long been understood by the CMS, providers, and the drug industry as an arbitrary but necessary cross-subsidy: Physicians in certain specialties (predominantly oncology, rheumatology, endocrinology, and nephrology) are reimbursed for their evaluation and management of patients at rates that do not cover their incomes and practice expenses; these shortfalls are recovered by the margin between what these providers are reimbursed for the injectable drugs they administer to patients and what they actually pay to purchase those drugs." Kleinke, J.D., "Re-Naming And Re-Gaming: Medicare's Doomed Attempt To Reform Reimbursement For Injectable Drugs," *Health Affairs*, December 8, 2004, W4-561–W4-571 at W4-562.

[239] See, for example, Spahn Deposition (Anthem BCBS), pp. 109–110, and 2000 Ashcroft Statement to the Senate, at S8022.

[240] MedPAC, *Physician-Administered Drugs: Distribution and Payment Issues in the Private Sector*, A Study conducted by NORC, August 2003, No. 03-4, p. 3.

[241] See section III.C.

some drugs may be quite large on a percentage basis (even if they are small in dollar terms).

4. Payors may use spreads to ensure provider participation in networks, which would require substantial reimbursements if some providers have market power

141. Payors compete for physicians to include in their provider networks,[242] and there was a significant amount of such competition in the 1990s.[243] To be competitive, cancer care centers must be adequately funded to allow them to attract physicians, provide efficient support staff, and use the latest technology.[244] Thus, payors have strong incentives to allow physicians to have a spread on drug purchases to encourage their participation.[245, 246, 247, 248] Payors have even substantially increased overall reimbursement rates (and therefore spreads) to maintain robust provider networks.[249]

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[242] See, for example, Deposition of Richard A. Francis (Reimbursement consultant, Harvard Pilgrim Health Care), September 20, 2004 ("Francis Deposition"), pp. 5–6, 22; Owens Deposition (Independence BC), pp. 49–50.

[243] Owens Deposition (Independence BC), pp. 49–50.

[244] Dougherty and Hagin, 1989, pp. 1, 18–20 at 19–20.

[245] MedPAC, *Survey of Health Plans Concerning Physician Fees and Payment Methodology*, A study conducted by Dyckman & Associates, August 2003, No. 03-7, p. 18.

[246] Anthem BCBS was aware that it had to pay providers competitive rates in order to maintain an adequate provider network. See Spahn Deposition (Anthem BCBS), pp. 53–55, 63–64.

[247] Blue Cross Blue Shield of Massachusetts was concerned that reducing fees under ASP reimbursement might lead to physicians withdrawing from their provider network, rendering it unviable. See Mulrey Deposition (BCBSMA), pp. 129–130.

[248] According to Professor Berndt: "Specifically, with physician-administered drugs, health plans/insurers risk losing valued physicians from their specialty networks (with all the implications that has for the competitiveness and relative attractiveness of the plans they offer employers) if they move patients from medical to pharmacy benefits and contract through specialty pharmaceuticals or PBMs for purchasing these drugs, instead of letting physicians capture the benefits of purchasing the drugs themselves and implicitly reselling them to payors. As a result, payors may not be quite as aggressive in obtaining cost information about these drugs, as they would be were they dealing with pharmacy-dispensed drugs"; Berndt Report, ¶ 108. "Even if they do invest in such information gathering activities, if health plans shift to a third-party supplier of the physician-administered drugs, they thereby might risk losing scarce specialty physicians from their physician network who have profited from the 'spread'"; Berndt Report, ¶ 188.

[249] See, for example, Owens Deposition (Independence BC), pp. 193, 201–202 (standard fee schedule plus 13 to 14 percent).